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Guidance for the Reregistration of Pesticide Products Containing Amitrole as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING AMITROLE AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme, giving preference to pesticides used on food and feed crops. Amitrole is in the H-7 herbicide cluster for chemicals used on drainage ditches, rights-of-way, forests and ponds.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end-use (formulated) products that contain the active ingredient. If we find serious concerns, we will bring end-use products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that registrants submit data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, it is the Agency's policy under §3(c)(2)(B) that these data are not required to be submitted by those registrants who qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of

the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA may issue a notice of intent to cancel or suspend the registration of any currently registered product or deny any application for registration of a product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Acting Administrator, EPA was enjoined from implementing §3(c)(1)(D) of FIFRA. EPA has decided that as long as this injunction is in effect, it will, for most pesticides, proceed with the requirements in this Guidance Document which do not require compliance with the provisions of §3(c)(1)(D). Despite this decision, EPA will require current registrants to apply to amend their product registrations to make changes in the labeling, packaging, or composition for this chemical. The Agency will supplement the Document with additional guidance when this litigation concludes. Failure to comply with the provisions of the subsequent guidance may also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This chapter describes the regulatory position of the Environmental Protection Agency ("the Agency") on amitrole, based on an evaluation of all registered manufacturing-use products (MUP's) containing amitrole as the sole active ingredient. Future requests for registrations of substantially similar products will be covered by this standard. Dissimilar products will require amendments to the standard. This standard provides the rationale for the Agency's position, the criteria for registration and also discusses labeling requirements and tolerances.

In developing its regulatory position, the Agency determines whether available data indicate that a pesticide has met the criteria for unreasonable adverse effects found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR). Pesticides meeting these criteria are candidates for a Special Review, an intensive risk/benefit analysis which a modification of the Rebuttable Presumption Against Registration (RPAR) process. The Agency's determination as to whether any criteria have been met and its rationale for any regulatory action are summarized in the regulatory position of this standard.

"Amitrole" is the accepted common name for 3-amino-1,2,4-triazole recognized by the American National Standards Institute. Trade and other names for amitrole include Weedazole®, Amino Triazole Weed Killer®, Cytrol®, Amitrol T®, Domatol®, Vorox®, Amizole®, X-All®, Ustinex®, AT, ATA, Aminotriazole 90 and Chempar Amitrole. The Chemical Abstracts Service (CAS) Registry number is 61-82-5. The Office of Pesticides Program's internal control number (EPA Shaughnessy number) is 004401.

B. USE PROFILE

Amitrole is a broad spectrum herbicide effective against a wide range of monocotyledonous (grasses) and dicotyledonous (broadleaf) weeds. It was first registered in 1948 for use on noncrop lands and in 1958 for use on cranberries on a no residue basis for postharvest application only.

Amitrole is registered for use on a variety of noncrop sites, including rights-of-way, marshes and drainage ditches, ornamentals and around commercial, industrial, agricultural, domestic, and recreational premises. It is formulated into a soluble concentrate/liquid (2 lbs/gal), soluble concentrate/solid (50 and 90%) and pressurized liquids (0.36 and 1%).

Amitrole is not currently registered for use on food crops. Registrants were notified by EPA on June 16, 1971 that registrations of all formulations containing amitrole and

bearing use directions for food crops would be cancelled because this chemical is a carcinogen in experimental animals. There are no tolerances for any food crop or water which will be used for irrigation, drinking, or other domestic purposes, and to date no new registrations or establishment of tolerances for amitrole have been requested.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on amitrole, the Agency has made the following determinations:

1. Amitrole has oncogenic potential and is a candidate for Special Review. Registrants of amitrole products are hereby notified that some uses of amitrole may have met the risk criterion for oncogenicity in 40 CFR 162.11(a). A Notice announcing the Agency's decision to initiate a Special Review will be published in the Federal Register.

2. The Agency will not reregister any current products and it will not register any new products containing amitrole at this time.

3. Except for homeowner uses, the oncogenic risk associated with all use patterns and application techniques of amitrole may be high and their continued general use may cause unreasonable adverse effects. Except for homeowner uses, all use patterns and application techniques are classified as restricted.

4. Registrants must alter labeling, as specified below, in order to maintain existing registrations or to permit new amitrole registrations. Labeling must include a cancer warning statement and a requirement to use protective clothing to reduce risk during the period of pivotal data development and Special Review.

5. Within 90 days after receipt of this Standard, registrants must: (A) commit to perform all of the required studies, (B) complete labeling of all products to-be-released-for-shipment, (C) furnish all retailers and wholesalers of record with supplementary labeling for all products in channels-of-trade, and (D) submit copies of the above labeling to the Agency as evidence of compliance with this

Standard. Within 180 days after receipt of this Standard, registrants must submit all pivotal data and initiate steps to fulfill the remaining data requirements. All registrants, regardless of whether they intend to maintain their registrations, are required by this Standard to furnish all retailers and wholesalers of record with supplementary labeling for all products in channels-of-trade.

6. Manufacturing-use pesticide products containing amitrole as a sole active ingredient may, after further review, be registered for sale, distribution, formulation and use in the United States, subject to the terms and conditions specified in this standard. Registrants and applicants with products that do not conform to this standard must apply to amend the standard in order to reregister and register, respectively. Mixtures and end-use products containing amitrole are covered under this standard for the purposes of labeling. The use patterns of the end-use products are considered for purposes of determining generic data requirements for amitrole.

7. Registrants not qualifying for a formulator exemption must provide or agree to develop all data specified in the tables of this standard to maintain existing registrations or to permit new amitrole registrations. The Agency may amend this standard or initiate further regulatory actions after it has reviewed the submitted data. All data must be generated according to the Good Laboratory Practices specified in 48 FR 53946.

8. Some of the required data will permit the Agency to perform a more accurate exposure assessment and determine the necessity for further regulatory action. Specifically, the Agency must be able to assess the ability of amitrole to penetrate the skin and the effectiveness of protective clothing. Due to their pivotal nature, registrants must initiate and submit these studies and initiate steps to complete the remaining data specified in the tables.

9. Food or feed uses of this pesticide will not be permitted to be registered.

10. End-use product label changes are required.

D. REGULATORY RATIONALE

Data indicate that amitrole has oncogenic potential. At this time, the Agency has determined that it will not reregister existing use patterns of amitrole for the following reasons:

1. Amitrole demonstrated oncogenic potential (thyroid and liver tumors) in laboratory rodent feeding studies. Risks associated with dietary exposure have been eliminated through cancellation of all food uses in 1971. No further food or feed uses will be permitted. Risks associated with mixer/loader/applicator exposure remain.

2. Toxicological data are insufficient to fully evaluate the hazards associated with dermal and inhalation exposure to this chemical.

3. Monitoring of workers applying amitrole showed no apparent changes in thyroid function. While the sole study on amitrole exposure did not adequately consider the effects of single or multiple episodic exposures on thyroid hormones, it did provide some evidence that brief exposures cause relatively minor or no effects on human endocrine systems.

4. The use of protective clothing specified in this standard and the restriction of high risk use patterns and application techniques of amitrole may reduce exposure. While it has no adequate data on the ability of amitrole to penetrate the skin, the Agency's evaluation of its structure and solubility indicates that some amitrole may penetrate the skin. Assuming 100 percent absorption and the results of the sole exposure study, workers associated with certain use patterns and application techniques are theoretically exposed to doses of amitrole approaching those which cause thyroid tumors in laboratory animals. It is estimated that protective clothing may reduce worker exposure approximately 80 percent or more, based on the structure and solubility of this chemical. This exposure reduction is anticipated to significantly reduce risk during the period of pivotal data development and permit continued registration under restricted use.

5. Given the scientific uncertainties associated with its preliminary analysis, the Agency will consult with experts in endocrinology and review the results of the pivotal data prior to deciding on how to further regulate this chemical. The Agency estimates that the risks associated with the use of this chemical for one year (i.e., the time required for instituting the changes required by this Standard) are low.

6. There are no data to estimate re-entry exposure to individuals entering areas treated with amitrole. The Agency will assess a need for a re-entry interval after it has reviewed the environmental and toxicological data required by this standard.

7. Available data are insufficient to fully assess the environmental fate of this chemical. A complete environmental fate assessment, including a review of the leaching potential of amitrole, will be performed after the required data is submitted to the Agency.

8. There are insufficient data to characterize the toxic effects of the end-use products of amitrole to aquatic organisms. A complete hazard assessment will be performed after additional ecological effects data are submitted to the Agency.

9. Available data on both human and wildlife poisoning incidents indicate that the majority of cases of human poisoning cited in the Pesticide Incident Monitoring System (PIMS) through June, 1981 appear to be the result of misuse or accident. The PIMS data provide no information on chronic health effects from exposure to amitrole.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

All products which contain amitrole are subject to this standard. The Agency will not consider registration of new products or reregistration of current products containing amitrole until it has reviewed the pivotal data required by this standard.

Should the Agency decide to register and reregister amitrole products after reviewing the pivotal data, registrants of products containing amitrole as the sole active ingredient must either comply with the acute toxicity limits, product composition, and use pattern requirements listed in Section F of this document; or submit data and a justification to amend the standard to encompass such products.

Should the Agency decide to register and reregister amitrole products after reviewing the pivotal data, applicants for registration and reregistration of products which contain amitrole as the sole active ingredient must comply with all terms and conditions described by this standard, including commiting to fill data gaps on a schedule agreed to by both this agency and the applicant, and when applicable, offering to pay compensation for data to the extent required by § 3(c)(1)(D) FIFRA. Applicants for registration under this standard must follow the instructions contained in this standard and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 90 percent amitrole as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the manufacturing-use amitrole products must be substantially similar to currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will require an amendment to the standard.

2. Acute Toxicity Limits

Technical grade and manufacturing-use products containing amitrole in acute toxicity category I, II, III, or IV must bear appropriate precautionary labeling.

3. Use Patterns

Manufacturing-use products containing amitrole must be labeled for formulation only into end-use products for use as herbicides to control grasses and broadleaf weeds in rights-of-way, marshes and drainage ditches, ornamentals, and around commercial, industrial, agricultural, domestic, and recreational premises. The attached index lists all registered uses for end-use products, which may be formulated from the manufacturing-use products covered by this standard, as well as approved maximum application rates and frequency.

Formulations may be applied by using helicopter or ground equipment, with the specific type of equipment determined by the conditions of the site and equipment availability.

The Agency classifies all uses patterns and application techniques, except homeowner uses, as restricted.

G. REQUIRED LABELING

Registrants must complete all label requirements within 90 days from the receipt of this guidance document. Products to be released for shipment or advertized, products which have been amended to remove any restricted uses, existing stocks of products covered by this document, related brochures, technical pamphlets and similar materials must be labeled to comply with all label requirements within 90 days after the receipt of this guidance document.

All technical grade, manufacturing-use, and end-use products containing amitrole must bear appropriate labeling as specified in 40 CFR 162.10. The following labeling requirements apply to technical, manufacturing-use, and end-use products.

1. Manufacturing-Use Product Statements

a. Use Patterns

Products intended for formulation into end-use products must bear the following statement:

"For formulation only into end-use herbicide products intended for noncropland, outdoor use."

"The use of this product may be hazardous to your health. This product contains amitrole, which has been determined to cause cancer in laboratory animals. Products intended for formulation into restricted-use pesticides must require on its labeling that a respirator be worn during mixing and loading. Lightweight waterproof clothing (jumpsuit [or coverall], boots [or shoes], gloves, and a wide-brimmed plastic hardhat) must be worn when mixing and loading all products and when applying all products to control dense, tall vegetation. Workers applying this product in all other situations must wear lightweight waterproof gloves and boots (or shoes). Products intended for formulation into general-use pesticides must require on its labeling that waterproof gloves be worn while handling the product."

All products must bear the following statements:

"Each formulator is responsible for obtaining EPA registrations for its formulated product(s)."

b. General Warning

"Do not discharge into lakes, streams, ponds, or public waters unless in accordance with NPDS permit. For guidance, contact your Regional Office of the EPA."

2. End-Use Product Statements

a. General Warnings and Limitations

All restricted-use products must bear the following statements:

"Restricted Use Pesticide"

"For retail sale to and application only by certified applicators or personnel under their direct supervision."

"The use of this product may be hazardous to your health. This product contains amitrole, which has been determined to cause cancer in laboratory animals. Wear a respirator during mixing and loading of all products. Wear lightweight waterproof clothing (jumpsuit [or coverall], boots [or shoes], gloves, and a wide-brimmed plastic hardhat) when applying all products to control dense,

tall vegetation. Workers applying this product in all other situations must wear lightweight waterproof gloves and boots (or shoes)."

All homeowner products must bear the following statements:

"The use of this product may be hazardous to your health. This product contains amitrole, which has been determined to cause cancer in laboratory animals. Wear waterproof gloves when using this product."

All products must bear the following statements, regardless of classification:

"Do not allow spray or spray drift to contaminate edible crops or water intended for irrigation, drinking or other domestic purposes."

"Do not allow livestock to graze or feed in treated non-crop areas."

All products intended for nonaquatic uses must bear the following statement on the label:

"Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes."

All products intended for aquatic uses must bear the following statement on the label:

"Consult your state Fish and Game Agency before applying this product to public waters. Permits may be required before treating such waters."

H. TOLERANCE REASSESSMENT

There are no established tolerances for amitrole in the U.S.A., Canada, and Mexico. There are no food or feed uses in the U.S.A. and residues are not permitted on any food, feed or water intended for irrigation, drinking, or other domestic purposes, and to date, no new registrations or establishment of tolerances for amitrole have been requested.

I. PRELIMINARY ANALYSIS OF CURRENT BENEFITS AND RISKS

1. Current Benefits Review

a. Introduction

The Agency has completed a current benefits review for amitrole. The review was based on published pesticide data and preliminary telephone discussions with users and applicators.

b. Usage Site of Study

This review summarized the data available on the pesticide applications on highway rights-of-way. This site was selected for analysis because it is the site on which the greatest volume of amitrole (approximately 50 percent of the annual production) is used and for which data are available. Lesser amounts of the herbicide are also used on utility-commercial-industrial-institutional sites with small amounts also used in forestry, aquatic areas and the home. Finally, the effectiveness of amitrole on poison ivy is viewed as particularly important by individuals sensitive to the toxic effects of this plant. However, the total volume used on poison ivy is small.

Amitrole is imported and is not produced in the United States. Currently 500,000 to 800,000 pounds of Active Ingredient (A.I.) are imported annually. The market for amitrole has shown little annual fluctuation during the last ten years. The three major importers are Union Carbide, American Cyanamid and Aceto Chemical. Amitrole use represents about 5 percent of the total herbicide used for vegetation control on highway rights-of-way. It is used by a large number of state and local agencies on an estimated 100,000 acres at a rate of 2.5 to 4 pounds per acre. Eleven states, particularly in the west, account for most of its use.

c. Benefits

Vegetation control on highway rights-of-way is needed in order to assure (1) safe shoulders for emergency exit from the roadway (i.e. grass must be long enough to protect the bank from erosion but short enough so as not to obscure obstructions), (2) adequate visibility at intersections; (3) that the roadway is unobstructed by brush or, where snow melting is important, the tree canopy does not overshade the road, and (4) weed-free appearance of ornamental plants. The major role of amitrole is to give non-selective contact weed control, either alone or in combination with longer-lasting herbicides, on those parts of shoulders where no vegetation is desired (e.g. immediately adjacent to the pavement, or under rails and around sign posts, where mowing is difficult).

Benefits from the use of amitrole are associated with its relatively low cost, broad-spectrum control of growing plants and the ability to mix it with other low cost, broad-spectrum residual soil active chemicals. In combination with other chemicals, low cost broadspectrum control is obtained both on newly emerged or established broadleafs by amitrole as well as seasonal control by residual product(s) with which it is mixed.

d. Substitutes

Amitrole substitutes are divided into two classes: herbicidal chemical control and non-herbicidal mechanical control.

1) Herbicidal Control

A limited number of nonselective, broad-spectrum postemergent substitutes are available for amitrole. These substitutes may be divided into contact herbicides and residual soil-active herbicides. The amine salts of dicamba, 2,4-D, MCPP and glyphosate are substitutes in the first category of contact herbicides. Glyphosate is as effective as amitrole in the control of emerged weeds and has little residual action, is more costly and more corrosive than amitrole and may lose some of its activity when tank-mixed with residual herbicides. The amine salts of dicamba, 2,4-D, and MCPP, while relatively inexpensive, can volatilize in hot weather and damage sensitive crops and shoulder plants. Additionally, dicamba can move through soils and damage woody vegetation.

Residual soil-active herbicides offer an advantage of longer control and lower cost than amitrole. In order to offer season-long control, these chemicals must be applied early in the season at high rates, a situation which could result in off-target movement of the pesticide, vegetation removal and soil erosion. Additional substitutes may be used, but not necessarily at lower cost, equal convenience or equal effectiveness.

2) Non-Herbicidal Control

Controlling brush on highway rights-of-way without herbicides by manual or mechanical cutting and controlled burning are high cost alternatives. Non-chemically controlled sites along guardrails and steep slopes are particularly high cost and are precisely the areas where amitrole is used.

e. Current Review of the Economic Impacts of Cancellation on Highway Rights-of-Way

The Agency has estimated that the financial impact of withdrawing amitrole could account for about a 1 to 3 million dollar cost increase to users. This estimate is based on users continuing to use a contact herbicide (specifically substituting glyphosate for amitrole) in combination with a residual herbicide.

The Agency's preliminary estimate does not take into account that some users may elect not to shift to another contact herbicide but rely entirely on residual herbicides. The Agency's preliminary information does not permit an estimate of the extent that users would elect another contact herbicide in place of amitrole as opposed to relying solely on the

use of residual pesticides for germination control. The Agency's current benefit review may change upon receipt of new information.

2. Preliminary Risk Analysis

a. Introduction

Data indicate that amitrole induces a high incidence of thyroid tumors in laboratory animals. Amitrole has also been shown to induce liver tumors in mice at feeding levels in excess of the maximum tolerated dose; thyroid carcinomas were evident in conjunction with liver tumors. Amitrole is a textbook example of a potent antithyroid agent in laboratory animals. The postulated mechanism of action is an alteration of the complex feedback mechanism between two endocrine glands, the thyroid and the pituitary. Dietary administration of amitrole inhibits peroxidase activity in the liver and thyroid, causing a subsequent inactivation of iodide ions in the blood. The lower level of active iodide ion reduces the level of thyroid hormones circulating in the blood. The reduced level of thyroid hormones induces the pituitary to secrete a hormone which stimulates the thyroid. Prolonged stimulation causes thyroid enlargement, hyperplasia and, ultimately, tumors.

The Agency's preliminary risk analysis is based on production data supplied by manufacturers, usage information, estimates supplied by consumers and worker exposure estimates. Worker exposure estimates were obtained through surrogate studies employing other pesticides with uses and application techniques similar to amitrole and the only exposure study (GS009517) which specifically used amitrole. The Agency's assumptions to estimate worker exposure are conservative and tend to err in the direction of overestimating exposure.

b. Exposure Assumptions

The following assumptions were used to estimate worker exposure:

1) All workers are unprotected, wearing cotton work clothes, short-sleeved shirt, without hat, gloves or respirator, with 15 percent of the body surface uncovered by clothing.

2) Applicator exposure was calculated from surrogate data by two possible methods. In the first and preferred method amitrole exposure varies as a linear function of the pounds of amitrole active ingredient expected to be used vs. the pounds of applied surrogate active ingredient. When no data were available, applicator exposure was calculated as a linear function of the duration of application and the concentration of the active ingredient in the spray.

3) Mixer/loader exposures were estimated from surrogate data and is proportional to the amount of amitrole active ingredient vs. the amount of surrogate active ingredient.

4) Highway tractor (or truck) applicators and forest helicopter applicators are tended by mixer/loader personnel. Except for home-use pressurized aerosols, all other applicators will also be involved in mixing/ loading operations.

c. Exposure Estimates

The Agency estimated the exposure for each technique of amitrole application, with the ranges for a particular technique based on actual field observations. The typical exposure is based on the average field worker exposure, while the minimum and maximum values are the lowest and highest exposures observed in the data. No exposure estimates were made for re-entry personnel. An exposure assessment of re-entry personnel will be made upon submission of data requested by this standard. The following table summarizes the Agency's exposure estimates for mixers, loaders and applicators.

PRELIMINARY EXPOSURE ESTIMATES

Exposure Situation	Minimum	Typical	Maximum
		(mg/kg/dy)*	
Utility			
Knapsack/Hand-Carry			
Applicator	$7x10^{-3}$	$4x10^{-2}$	$9x10^{-2}$
Mixer/Loader	$2x10^{-3}$	$9x10^{-3}$	$2x10^{-2}$
Power Wagon			
Mixer/Loader/ Applicator	$3x10^{-2}$	$3x10^{-1}$	$8x10^{-1}$
Industry			
Knapsack/Hand-Carry			
Applicator	$5x10^{-3}$	$3x10^{-2}$	$7x10^{-2}$
Mixer/Loader	$5x10^{-4}$	$3x10^{-2}$	$1x10^{-1}$
Power Wagon			
Mixer/Loader/ Applicator	$3x10^{-2}$	$3x10^{-1}$	$8x10^{-1}$
Railroad			
Tanktrain			
Applicator	$4x10^{-5}$	$2x10^{-4}$	$5x10^{-4}$
Mixer/Loader	$8x10^{-3}$	$4x10^{-2}$	$9x10^{-2}$
Hy-Rail			
Applicator	$4x10^{-6}$	$2x10^{-5}$	$5x10^{-5}$
Mixer/Loader	$1x10^{-4}$	$4x10^{-3}$	$1x10^{-2}$
Forest			
Knapsack/Hand-Carry			
Applicator	$4x10^{-4}$	$3x10^{-3}$	$5x10^{-3}$
Mixer/Loader	$1x10^{-4}$	$7x10^{-3}$	$3x10^{-2}$
Helecopter			
Pilot	$2x10^{-4}$	$3x10^{-4}$	$4x10^{-4}$
Mixer/Loader	$2x10^{-3}$	$7x10^{-2}$	$3x10^{-1}$
Highway			
Tractor/Truck			
Applicator	$2x10^{-5}$	$1x10^{-4}$	$3x10^{-4}$
Mixer/Loader	$5x10^{-3}$	$3x10^{-2}$	$6x10^{-2}$
Home			
Aerosol Can			
Applicator	$3x10^{-7}$	$1x10^{-5}$	$2x10^{-5}$

*mg/kg/dy (Human Equivalents) =(dose/20)/3
Lifetime Exposure =(mg/dy)(dys/yr)/(70kg)(2)(365)

In summary, the Agency has made a preliminary estimate that dermal exposure, especially from the hands, constitutes virtually all of the total amitrole exposure. The use of lightweight waterproof clothing (jumpsuit, gloves, hat and boots [or shoes]) is expected to reduce dermal exposure. Despite the minor contribution toward the total exposure, a respirator is required during mixing/loading operations until the effects of inhalation exposure can be better defined.

d. Risk Estimates

The Agency cannot, with the available data, accurately predict the risks involved with the use of amitrole. Quantitative risk assessments are normally based upon assumptions and,

consequently, contain uncertainties. The amitrole risk assessment contains more uncertainty than usually encountered because of the lack of information about dermal absorption. The choice of the most significant assumptions used to calculate the risks associated with the use of this chemical are explained in the discussion below which highlights the principal areas of scientific uncertainty that preclude the development of a more definitive estimate of risk.

1) Dermal Penetration

Exposure to applicators or spray workers is the major source of exposure as there are no food uses and other incidental contact with this chemical would be minimal. Data indicate that exposure to applicators is almost entirely by the dermal route. Therefore, dermal penetration is a very important parameter to estimate worker exposure. No data are currently available to estimate the extent of dermal penetration. In the absence of data, the Agency assumes 100 percent dermal penetration, a worst case scenerio. Realistically, the Agency feels that much less than 100 percent dermal penetration, based on the structure and solubility of this chemical.

The effect of dermal penetration on the risk associated with the use of this chemical is demonstrated by the two estimates of dermal penetration, 0.1 percent and 100 percent. These two estimates of dermal penetration represent a worst case absorption and the lowest value which can be usually be demonstrated.

2) Risk Assessment Model

The Agency has utilized both the linear one-hit model and the log-probit model to estimate cancer risk associated with worker exposure to amitrole. Estimates by both models are presented in the risk estimate tables. The Agency believes that the log probit model is most appropriate to express the risk based on the data showing induction of thyroid tumors and estimates realistic limits of risk, while the one-hit model provides an upper limit of risk estimation.

Both models demonstrate similar risk estimates at high dose levels, primarily because the estimated human exposure levels approach the level of dosing in animal studies. This convergence of exposure precludes the necessity for extensive extrapolation at high levels of exposure. The risk estimates diverge radically, though, at medium and low dose levels.

3) Thyroid Extrapolation

The extrapolation of oncogenic animal data to humans is an area of uncertainty. Although the Agency has usually approached extrapolation by adjusting equivalence of exposure based on surface areas between animals and humans, the amitrole risk assessment contains additional uncertainties because of interpretation of data on thyroid effects. It is not known

whether a direct comparision can be made between rat and human thyroids or whether a correction factor should be used. Regardless of this latter uncertainty, the Agency believes that the human thyroid can probably withstand a greater insult than the rat thyroid. It is the Agency's policy to presume that effects demonstrated in laboratory animals have the potential to occur in humans. This issue will be carefully studied during the course of the Special Review for this chemical.

4) Basis of Risk Estimates

The Agency utilized a study by Johnson et al. (1981) (GS009504) in its risk estimates because the dietary dosing schedule was the most representative of the "pulsed" exposures that are experienced by applicators and the histological evaluation demonstrated a clear dose-response relationship. Additionally, this study dosed rats with amitrole at levels comparable to the highest human exposure estimates.

Dermal absorption was assumed to be 100 percent because no acceptable dermal absorption data on amitrole are available. A worker was assumed to weigh 70 kg, have a work exposure of 35 years over a 70 year lifetime, and wear no specialized protective clothing during mixing/loading/application.

The positive steady dosing oncogenicity studies were not used for the quantitative risk assessment because that dosing pattern was less appropriate to the intermittant pattern of applicator exposure than the pulsed study. These studies also utilized dosing at levels that are somewhat higher than the lifetime average doses administered in the pulsed study. An assessment utilizing the linear model and a steady dose would produce risk estimates no higher than those based on the pulsed study. The risk assessment estimates that the liver oncogenic risk is less than the thyroid oncogenic risk, based on the linear model. Thus, estimates based on the linear model are a clear upper limit of worker risk.

The following tables, for comparison, demonstrate worker risk utilizing the linear and log-probit models both applied to the data showing induction of thyroid tumors. Dermal absorption estimates of 100 percent and 0.1 percent, respectively, are used in the following tables.

PRELIMINARY RISK ESTIMATE RANGES
(100 % Dermal Absorption)

Exposure Situation	Model Type	
	Log-Probit	One-Hit
Utility		
Knapsack/Hand-Carry		
Applicator	$<10^{-8}$-10^{-3}	10^{-2}->10^{-1}
Mixer/Loader	$<10^{-8}$	10^{-3}-10^{-2}
Power Wagon		
Mixer/Loader/ Applicator	10^{-8}->10^{-1}	10^{-2}->10^{-1}
Industry		
Knapsack/Hand-Carry		
Applicator	$<10^{-8}$-10^{-4}	10^{-2}->10^{-1}
Mixer/Loader	$<10^{-8}$->10^{-1}	10^{-3}->10^{-1}
Power Wagon		
Mixer/Loader/ Applicator	$<10^{-8}$->10^{-1}	10^{-2}->10^{-1}
Railroad		
Tanktrain		
Applicator	$<10^{-8}$	10^{-4}-10^{-3}
Mixer/Loader	$<10^{-8}$-10^{-3}	10^{-2}-$<10^{-1}$
Hy-Rail		
Applicator	$<10^{-8}$	10^{-5}-10^{-4}
Mixer/Loader	$<10^{-8}$	10^{-4}-10^{-2}
Forest		
Knapsack/Hand-Carry		
Applicator	$<10^{-8}$	10^{-3}-10^{-1}
Mixer/Loader	$<10^{-8}$-10^{-7}	10^{-4}-10^{-1}
Helecopter		
Pilot	$<10^{-8}$	10^{-4}-10^{-3}
Mixer/Loader	$<10^{-8}$->10^{-1}	10^{-3}->10^{-1}
Highway		
Tractor/Truck		
Applicator	$<10^{-8}$	10^{-5}-10^{-3}
Mixer/Loader	$<10^{-8}$-10^{-5}	10^{-2}-10^{-1}
Home		
Aerosol Can		
Applicator	$<10^{-8}$	10^{-6}-10^{-5}

* Ranges indicate minimum and maximum exposures

PRELIMINARY RISK ESTIMATE RANGES
(0.1 % Dermal Absorption)

Exposure Situation	Model Type	
	Log-Probit	One-Hit
Utility		
Knapsack/Hand-Carry		
Applicator	$<10^{-8}$	10^{-5}-10^{-4}
Mixer/Loader	$<10^{-8}$	10^{-6}-10^{-5}
Power Wagon		
Mixer/Loader/		
Applicator	$<10^{-8}$	10^{-4}-10^{-3}
Industry		
Knapsack/Hand-Carry		
Applicator	$<10^{-8}$	10^{-5}-10^{-4}
Mixer/Loader	$<10^{-8}$	10^{-6}-10^{-4}
Power Wagon		
Mixer/Loader/		
Applicator	$<10^{-8}$	10^{-4}-10^{-3}
Railroad		
Tanktrain		
Applicator	$<10^{-8}$	10^{-7}-10^{-6}
Mixer/Loader	$<10^{-8}$	10^{-5}-10^{-4}
Hy-Rail		
Applicator	$<10^{-8}$	10^{-8}-10^{-7}
Mixer/Loader	$<10^{-8}$	10^{-7}-10^{-5}
Forest		
Knapsack/Hand-Carry		
Applicator	$<10^{-8}$	10^{-6}-10^{-5}
Mixer/Loader	$<10^{-8}$	10^{-7}-10^{-4}
Helecopter		
Pilot	$<10^{-8}$	10^{-7}-10^{-6}
Mixer/Loader	$<10^{-8}$	10^{-6}-10^{-3}
Highway		
Tractor/Truck		
Applicator	$<10^{-8}$	10^{-8}-10^{-6}
Mixer/Loader	$<10^{-8}$	10^{-5}-10^{-4}
Home		
Aerosol Can		
Applicator	$<10^{-8}$	10^{-9}-10^{-8}

* Ranges indicate minimum and maximum exposures

There is wide variation in risk estimation. These variations depend on the model used to estimate risk and the percent of dermal absorption used in the exposure estimates. The Agency has made a preliminary estimate that a high risk may be associated with all uses, except for the homeowner use. Homeowner risk is estimated to be low because exposure is estimated to be one hour per year and the chemical is applied as a targeted (non-fogging) spray.

Despite the potential for high risk, the Agency believes that restriction of all uses patterns and application techniques (except homeowner uses) and the use of protective clothing will reduce exposure 80 percent and reduce risk

associated with the use of this chemical during the period of pivotal data development. The exposure associated with the homeowner use will be reduced by the use of waterproof gloves.

The Agency's preliminary analysis of the effects of restricting all use patterns and application techniques, except the homeowner use, coupled with the use of protective clothing indicates that exposure and, hence, risk will be reduced for all use patterns and application techniques except the power wagon application of amitrole.

3. Conclusions

The Agency has determined that amitrole may have exceeded the oncogenicity risk criteria for Special Review.

The Agency has made a preliminary determination that the costs of cancellation to be a 1 to 3 million dollar cost increase to users, while the benefits of continued use are to provide for the safe use of highways. The Agency has made a preliminary determination that the risk associated with some uses is high. Restriction of all uses, except the homeowner use, and labeling will mitigate risk during the period of pivotal data development and Special Review. The Agency considers the establishment of the dermal absorption of amitrole and the effectiveness of protective clothing to be pivotal in its future risk assessment.

Pending further review, registration of new products and reregistration of current products containing amitrole cannot be permitted until the Agency has reviewed these pivotal data.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.120 Product Chemistry				
Product Identity				
61-2 - Statement of Composition	TGAI	Partially 2/	00052653 00052652	Yes/6 months
61-3 - Discussion of Formation of Unintentional Ingredients	TGAI	No		Yes/6 months
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No		Yes/6 months
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00052652	No
63-3 - Physical State	TGAI	Yes	00052652	No
63-4 - Odor	TGAI	Yes	GS009514	No
63-5 - Melting Point	TGAI	Yes	00052652	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes/6 months

1/ Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
2/ Details of the laboratory synthesis procedures are given. However, details of the actual manufacturing procedures presently being used needs to be supplied by all registrants.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.120 Product Chemistry (cont'd)				
63- 8 - Solubility	TGAI OR PAI	Partially 2/	00052652 00033124 00069171	Yes/6 months
63- 9 - Vapor Pressure	PAI	No		Yes/6 months
63-10 - Dissociation Constant	PAI	No		Yes/6 months
63-11 - Octanol/water partition coefficient	PAI	No		Yes/6 months
63-12 - pH	TGAI	Yes	00052652	No
63-13 - Stability	TGAI	Yes	00052652	No
Other Requirements				
64- 1 - Submittal of samples	Choice	No		Yes/6 months

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Solubilities in quantitative terms are needed.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation		Data Be Submitted Under FIFRA Section 3(c)(2)(B)?When?
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	B,D,G,H	No			Yes/6 months
PHOTODEGRADATION:						
161-2 - In water	TGAI or PAIRA	B,D,G	No			Yes/6 months
161-3 - On soil	TGAI or PAIRA	G	No			Yes/6 months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	B,G,H	Partially 3/	00036962 00027115	00033127 00089104	Yes/24 months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D,G	No			Yes/24 months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No			Yes/24 months

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Studies 00036962, 00033127, 00089104 , and 00027115, partially satisfy the aerobic soil metabolism data requirements by providing data on the rate of degradation of amitrole in several soil types. No data were provided on the formation and decline of degradation products of amitrole in aerobic soil other than $^{14}CO_2$ (00027115).

TABLE A

GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation		Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.130 Environmental Fate (cont'd)						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	B,D,G,H	Partially 3/	00032045	00044017	Yes/6 months
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	B,G,H	No			Yes/24 months
164-2 - Aquatic (Sediment)	TEP	D	No			Yes/24 months
164-3 - Forestry	TEP	G	No			Yes/24 months
164-5 - Soil, Long-term	TEP	B,D,G,H	No			Reserved 4/

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ These soil thin layer chromatography studies fulfill the rapid leaching part of the mobility data requirement for the noncrop use patterns by providing information on the movement (R_f values) of amitrole on sand, sandy loam, silt loam, clay loam, and silty clay loam thin layer plates. To totally satisfy the mobility data requirements the following studies are required. 1) A mobility study to assess the leaching potential of amitrole and its degradates after the pesticide has been aged in sandy loam soil or a soil representative of the use area. This will satisfy the data requirement for noncrop use patterns. 2)A batch equilibrium (adsorption/desorption) study on a sandy soil or a soil representative of the domestic use area. This will satisfy the data requirement for the domestic outdoor use pattern. 3) A batch equilibrium (adsorption/desorption) study on one aquatic sediment obtained from a representative aquatic use area. This will satisfy the data requirement for the aquatic noncrop use pattern. 4) A soil thin layer chromatography, soil column, or a batch equilibrium (adsorption/desorption) study on a soil representative of the use area (forest). This will satisfy the data requirement for the forestry use pattern.

4/ The requirement for Dissipation: Long Term Studies is reserved depending upon the results of the Field Dissipation Study

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.130 Environmental Fate (cont'd)					
ACCUMULATION STUDIES:					
165-3 - Irrigated Crops	TEP	D	No		Yes/24 months
165-4 - In Fish	TGAI or PAIRA	B,D,G	Yes	00061349	No
165-5 - In Aquatic Non-Target Organisms	TEP	D,G	No		No 3/
SPECIAL EXPOSURE STUDIES:					
- Protective Clothing Effectiveness	TEP	B,D,G	No	-	Yes/6 months
- Exposure Study	TEP	B,D,G	Partially	GS009517 4/	No

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Accumulation studies in aquatic non-target organisms are required to support aquatic non-food and forestry use patterns. However, the accumulation studies for non-target organisms are waived because the data from the laboratory fish accumulation study did not show a potential for residues of amitrole to accumulate in bluegills.

4/ This study only evaluated worker exposure. A study to evaluate the effectiveness of the protective clothing is required. The Agency should be contacted for protocol review.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Oral LD_{50} - Rat	TGAI	B,D,G,H	Yes	00063598	No
81-2 - Dermal LD_{50}	TGAI	B,D,G,H	Yes	00063599	No
81-3 - Inhalation LC_{50} - Rat	TGAI	B,D,H	Yes	GS009502	No
81-4 - Primary Eye Irritation	TGAI	B,D,G,H	Partial	000063599 5/	Yes/6 months
81-5 - Primary Skin Irritation	TGAI	B,D,G,H	No		Yes/6 months
81-6 - Dermal Sensitization	TGAI	B,D,G,H	No		Yes/6 months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	B,D,G,H	No		No 3/
SUBCHRONIC TESTING					
82-1 - 90-Day Feeding - Rodent only	TGAI	B,D,G,H	Yes	00052658 00082174 00052643 00063601 00028434 00063598	No
82-3 - 90-Day Dermal	TGAI	B,D,G,H	Partially 4/	GS009517	Yes/24 months

1/ Composition: TGAI = Technical grade of the active ingredient.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Amitrole is not structurally related to a known neurotoxin nor does it inhibit cholinesterase.
4/ The study indicated that an unprotected worker could receive dermally 20.4 mg/kg/day of amitrole under test conditions. Medical monitoring of thyroid function was not assessed for a sufficient time period. Thyroid function must be monitored in the required study. Also, the ability of this chemical to be absorbed dermally must be quantified.
5/ The scoring system and eye irritation scores were not reported. These data must be provided or the test must be rerun.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.135 Toxicology (cont'd)					
82-4 - 90-Day Inhalation - Rat	TGAI	B,D,G,H	Partially 4/	GS009502 GS009517	yes/24 months
CHRONIC TESTING					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	B,D,G,H	Yes	00061351 00061348 00082176 GS009503 00061340 GS009504 GS009505 GS009520	No
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	B,D,G,H	Yes	00061351 00061348 00082176 GS009503 00061340 GS009504 GS009505 GS009518 GS009520	No
83-3 - Teratogenicity - 2 species	TGAI	B,D,G,H	Partially 3/	GS009506 GS009507	Yes/24 months
83-4 - Reproduction - 2-generation	TGAI	B,D,G,H	Yes	GS009506	No

1/ Composition: TGAI = Technical grade of the active ingredient.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=domestic Outdoor; I=Indoor.
3/ The two available studies were incomplete in reporting and design. The teratology study in mice (GS009506) did not measure the water consumption of the animals (amitrole was fed to the animals in the drinking water). The study in rats (GS009507) did not have visceral or skeletal examination of the fetuses.
4/ Thyroid function must be monitored in this study.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.135 Toxicology (cont'd)					
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	B,D,G,H	Yes 3/	00052661 00052647 00052660 00052649	No
84-2 - Chromosomal Aberration	TGAI	B,D,G,H	Yes 3/	00052665 05020819 00052662 05020822	No
84-2 - Other Mechanisms of Mutagenicity	TGAI	B,D,G,H	Yes 3/	00052646 GS009508 00052648 GS009509 00079923	No
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	B,D,G,H	Yes	00052659 00052645 00052644 GS009510 GS009511	No
- Dermal Absorption Study 4/	PAIRA	B,D,G,H	No		Yes/6 months

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a use-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ The citations apply to all mutagenicity testing.
4/ Contact the Agency for specific data requirements and protocol review.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?When?
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	B,D,G,H	No		Yes/24 months
71-2 - Avian Dietary LC_{50}	TGAI	B,D,G,H	Yes	00022923 5/	No
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	B,D,G,H	Yes	00025435 6/ 00069192 6/ GS009519 5/ GS009515 5/ GS009516 5/	No
	TEP	D	Partially 3/	00024959 6/	Yes/24 months
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	B,D,G,H	Partially 4/	GS009519 6/ 00017800 6/ 05001497 6/	Yes/24 months
	TEP	D	No		Yes/24 months
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	D	No		Yes/24 months
	TEP	D	No		Yes/24 months

1/ Composition: TGAI = Technical Grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ The formulated product tested was not representative of products used to control aquatic vegetation.
4/ The test was not performed according to the recommended procedures. Recommended test procedures call for testing the first instar stage as opposed to the mature stage of the organism. The former are generally more sensitive than the latter.
5/ This study fulfills Guideline requirements and supports registration.
6/ This study does not fulfill Guideline requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITROLE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	B,D,G,H	Yes	00036935	No

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING AMITROLE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation		Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.120 Product Chemistry					
Product Identity					
61-1 - Identity of Ingredients	MP	Yes	00052653	00052652	No
61-2 - Statement of Composition	MP	Partially 2/	00052653	00052652	Yes/6 months
61-3 - Discussion of Formation of Unitentional Ingredients	MP	No			Yes/6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	No			Yes/6 months
62-2 - Certification of Limits	MP	No			Yes/6 months
62-3 - Analytical Methods for Enforcement of Limits	MP	Partially 3/	00063956		Yes/6 months
Physical and Chemical Characteristics					
63-2 - Color	MP	Yes	00052652		No
63-3 - Physical State	MP	Yes	00052652		No
63-4 - Odor	MP	Yes	GS009514		No
63-7 - Density, bulk density, or specific gravity	MP	No			Yes/6 months

1/ Composition: MP = Manufacturing-use product.

2/ Details of the laboratory synthesis procedure are given. However, details of the actual manufacturing procedures presently being used have not been supplied by any of the registrants.

3/ Descriptions and validation data for analytical methods used must be submitted by each registrant.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING AMITROLE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? When?
§158.120 Product Chemistry (cont'd)				
63-12 - pH	MP	No		Yes/6 months
63-14 - Oxidizing or reducing action	MP	No		Yes/6 months
63-15 - Flammability	MP	No		Yes/6 months
63-16 - Explodability	MP	No		Yes/6 months
63-17 - Storage Stability	MP	No		Yes/6 months

1/ Composition: MP = Manufacturing-use product; Choice = Test substance choice determined on a case-by-case basis.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING AMITROLE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/ When?
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00063598	No 3/
81-2 - Dermal LD_{50}	MP	Yes	00063599	No 3/
81-3 - Inhalation LC_{50} - Rat	MP	Yes	GS009502	No 3/
81-4 - Primary Eye Irritation - Rabbit	MP	Partially 4/	00063599	Yes/6 months
81-5 - Primary Dermal Irritation	MP	No		Yes/6 months
81-6 - Dermal Sensitization	MP	No		Yes/6 months

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted within 8 months.

3/ This is based on the assumption that the manufacturing-use products are similar in composition to the technical product originally tested.

4/ The scoring system was not reported. Either the scoring system and scores should be forwarded or the test should be redone unless the pH is less than 2 or greater than 11.5; and the product will be classified Toxicity Category I on the basis of potential eye and dermal irritation effects.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix I) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1/] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted[2/]. Any necessary studies must be conducted in accordance with acceptable protocols, examples of which are contained in EPA's Pesticide Assessment Guidelines[3/], and, for the most part, in the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ U.S. EPA, 1982. Pesticide Registration; Proposed Data Requirements - Part 158. FEDERAL REGISTER of November 24, 1982 (47 FR 53192).

3/ U.S. EPA, 1983. Pesticide Assessment Guidelines, National Technical Information Service, Springfield, VA.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix III)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed.

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA will consider your request, you remain subject to the deadlines for submitting the required data until EPA grants your request.

(Footnote continued from previous page)
to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix IV) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 an V-2], as indicated by the following paragraphs of this chapter of the guidance document.

You must submit the revised labeling set forth in this guidance package within 90 days of receipt of this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix V-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-2. [40 CFR §162.10(b)]

Item 2. COMPANY NAME, ADDRESS AND PHONE NUMBER - The name, address and phone number of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-2. [40 CFR §162.10(c)]

Item 3. AVERAGE NET CONTENTS - An average net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The average net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the

largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-2. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-2. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-2. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and nominal percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients as indicated in your certification of limits. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-2. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "KEEP OUT OF REACH OF CHILDREN" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-2. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-2. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-2. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-2. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-2. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-2. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-2. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-2. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-2. [40 CFR §162.10(l)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-4 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-2. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Robert Taylor (PM 25)
Phone No. (703)-557-1800
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1 and revised labeling. Refer to Appendix II with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1).

Appendix I

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations under the Standard

MRID	CITATION
GS009518	Alexander, N.M. (1959) Antithyroid Action of 3-amino-1,2,4 triazole. Journal of Biological Chemistry 243:148-150.
00033124	American Chemical Paint Company (1955) Weedazol: H-60. (Unpublished study received Jun 9, 1955 under 264-68; submitted by Union Carbide Agricultural Products Co., Ambler, PA.; CDL: 001845-A)
00063956	American Cyanamid Company (1957) Crop Residue Data: Corn, soybeansm apples, cranberries. (Compilation; unpublished study received Mar 18, 1957 under 241-37; CDL:222312-E)
00089104	American Cyanamid Company (1959) Aminotriazole Residues in Soil. (Compilation; unpublished study, including published data, received May 16, 1960 under 241-37; CDL:120214-A)
00069171	American Cyanamid Company (1961) The Name, Chemical Identity, and Composition: Amino Triazole Weedkiller®: 3-amino-1,2,4-triazole. (Unpublished study received Nov 18, 1959 under 241-37: CDL:231111-G)
00036935	Atkins, E.L.; Greywood, E.A.; MacDonald, R.L. (1975) Toxicity of Pesticides and other Agricultural Chemicals to Honey Bees. Laboratory Studies. University of California, Division of Agriculture Science Leaflet 2287. 38 pp.
00052643	Babish, J.G. (1977) Triiodothyronine (T-3) and Thyroxine (T-4) levels in male rats consuming amitrole (3-amino, 1-2-4-triazole) in their diets for four weeks followed by a four-week recovery period; Laboratory No. 5539. (Unpublished study received Sep 22, 1980 under 264-135; prepared by Food and Drug Research Laboratories, Inc., submitted by Union Carbide Agricultural Products Co., Ambler, PA.; CDL:243310-A)
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GS009517	Baugher, D.G.; Bookbinder, M.G.; Blundell, M.S. (1982) Medical Monitoring and Assessment of Exposure of Workers Applying Amitrole to Utility Rights-of-Way. (Unpublished study received Nov 18, 1982; prepared by Dynamac Corporation; submitted by Union Carbide Agricultural Products Company, Inc., Research Triangle Park, NC.)

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00069192 Bond, C.E.; Lewis, R.H.; Fryer, J.L. (1960) Toxicity of Various Herbicidal Materials to Fishes. Pages 96-101, in Transactions of the 1959 Seminar of Biological Problems in Water Pollution. By Robert A. Taft Engineering Center. Cincinnati, Ohio: U.S. Public Health Service. (Technical Report W60-3; published study; CDL:230691-H)

GS009505 Bionetics Research Laboratories, Inc. (1968) Evaluation of Carcinogenic, Teratogenic, and Mutagenic Activities of Selected Pesticides and Industrial Chemicals. Vol. I: Carcinogenic Study. Report No. NCI-DCCP-CG-1973-1-1. (Prepared by Bionetics Research Laboratories, Inc., Bethesda, MD., prepared for National Cancer Institute, Inc., MD., August 1968; U.S. Department of Commerce, NTIS No. PB-223 159)

00052646 Brusick, D. (1975) Mutagenic Evaluation of Compound: 3-amino-1,2,4-triazole: 99.4%:LBI Project #2547. (Unpublished study received Sep 22, 1980 under 264-135; prepared by Litton Bionetics, Inc., submitted by Union Carbide Agricultural Co., Ambler, PA.; CDL:243310-D)

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00052648 Brusick, D. (1975) Mutagenic Evaluation of Compound: 3-amino-1,2,4-triazole: Final Report In Vitro Cellular Transformation in BALB/3T3 Cells: LBI Project No. 2549. (Unpub lished study received Sep 22, 1980 under 264-135; prepared by Litton Bionetics, Inc., submitted by Union Carbide Agricultural Products Co., Ambler, PA.; CDL:243310-F)

05020822 Carere, A.; Ortali, V.; Cardamone, G.; Torracca, A.M.; Raschetti, R.; (1978) Microbiological Mutagenicity Studies of Pesticides In Vitro. Mutation Research 57(3):277-286.

GS009502 Cox, G.E.; Re, T.A. (1978) Inhalation Toxicity Study with 3-amino-1,2,4-triazole (Amitrole) in Adult Fischer 344 Rats. Lab No. 5492. (Unpublished study prepared by Food and Drug Research Laboratories, Inc., submitted by Union Carbide)

00017800 Crosby, D.G.; Tucker, R.K. (1966) Toxicity of Aquatic Herbicides to Daphnia magna. Science 154(Oct 14):289-291. (Also in unpublished submission received Mar 17, 1976 under 38329-2; submitted by Cosolidated Chemical Co., Denver, Col.; CDL:225259-K)

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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				

63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermak sensitization				

cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by

any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for • • •," "Distributed by • • •," or "Sold by • • •" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(*A*) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F. if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing—*(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

Appendix V-2 (continued)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

FINAL SUMMARY
100-01

EPA Index to Pesticide Chemicals

AMITROLE*

TYPE PESTICIDE: Herbicide

FORMULATIONS: Tech (90%, 95%); WP (15%, 25%); F1C (0.33 lb/gal, 1%); SC/L (0.3 lb/gal, 2 lb/gal); SC/S (50%, 90%); PrL (0.36%, 1%)

GENERAL WARNINGS AND LIMITATIONS: For use as general weed killer in non-crop areas. Do not allow spray or spray drift to contaminate edible crops, or water which will be used for irrigation, drinking or other domestic purposes. Do not apply to water where fish are present. No residue in crops is permitted. Soil persistence: 2 to 4 weeks.

TIME REQUIRED FOR CONTROL: Ten days to 3 weeks.

PHYTOTOXICITY TO TARGET WEEDS: Albinism in developing foliage; senescence in mature leaves, wilting.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Disrupts chloroplast development; inhibits regrowth from buds; general growth inhibition; interferes with metabolism of nucleic acid precursors.

BROADLEAF WEEDS CONTROLLED:

CQBIBE	alfalfa	(b)
BFAWBB	canada thistle	(b)
ADABBA	carpetweed	
AZALAA	catchfly	
AZAAAC	chickweed	
BFATAA	chrysanthemum	(d)
ELAGAA	cinquefoil	
CQAAAB	clover	
BFDQAA	cocklebur	
AZAOBB	common chickweed	
BFDHAA	dandelion	
DAAHAA	dock	(a)
BKBFBA	field pennycress	
BFCNAA	groundsel	
CWABBA	hemp	(a)
CDABBA	hempnettle	
CDAFBA	henbit	
CWAIBB	horsenettle	(b)
GAAABJ	ivy	
CWADBD	jimsonweed	
DAAGAC	knotweed	
CDAIBA	kochia	(a)
CDAEAB	lambsquarters	
CWAGBE	leafy spurge	(b)

*3-amino-s-triazole
3-amino-1,2,4-triazole

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BROADLEAF WEEDS CONTROLLED (continued)

PAMAAAB	milkweed	(a)
PSGAAAB	morningglory	
PBFAJBN	mugwort	
PBKAAAC	mustard	
PFFARAA	pennywort	
PAAAABI	pigweed	(a)
PDXABAA	plantain	
PFMAFBB	puncturevine	
PAAAABP	purslane	
PBFAEAA	ragweed	
PBKAHBA	sheperdspurse	
PEAAGAD	smartweed	
PBFDCAA	sowthistle	(b)
PBVAGBK	spotted spurge	
PAAAABD	stinkweed	
PBFBUAA	sunflower	(a)
PAAAACD	tarweed	
PAAAAAX	thistles	
PAZAHBA	white cockle	
PBKAJAA	whitetop	(b)
PEAAGBH	wild buckwheat	
PBKADBB	yellow rocket	

(a) at 2 pounds active ingredient per acre.
(b) at 4 pounds active ingredient per acre.
(d) at 8 pounds active ingredient per acre.

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCACKBA	annual bluegrass	(a)
PCABMBB	barnyardgrass	(a)
PCAAZBA	bermudagrass	(d)(1)
PCACKAA	bluegrass	
PCAATBK	cheat	(a)
PCABFAA	crabgrass	
PCAATBM	downy brome	
PCACUAA	foxtail	(a)
PCABIBA	goosegrass	
PCACBAA	muhlenbergia	
PBMADAA	nutsedge	(b)
PCABBBA	orchardgrass	
PCAACBA	quackgrass	(b)(1)
PCACHBA	reed canarygrass	(1)
PCAATBI	ripgut brome	(b)(1)
PCABCAA	ryegrass	(a)
PCABRBA	velvetgrass	
PCABXBC	whitegrass	
PCABEBD	wild barley	(a)(1)
PCAACBB	wild oat	
PCTABEB	wild onion	

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GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

PCACE3C	witchgrass	

(a) at 2 pounds active ingredient per acre.
(b) at 4 pounds active ingredient per acre.
(d) at 8 pounds active ingredient per acre.
(l) suppression only.

WOODY PLANTS CONTROLLED:

PDMACAA	ash	(f)
PBWAFBS	bear oak	(h)
PACABBC	bigleaf maple	(g)
PAYAEBC	buckbrush	(f)
PELAPAA	cherry	(f)
PAYACAA	honeysuckle	(g)
PCQBPBA	kudzu	(g)
PCQBQAA	locust	(f)
PBWAFCN	northern red oak	(h)
PAHABBI	poison ivy	(e)
PAHABBJ	poison oak	(e)
PENACBA	pricklyash	(f)
PELATBL	salmonberry	(g)
PAHABAA	sumac	(f)
PELATBO	western dewberry	(g)
PDMACBA	white ash	(h)
PBWAFBB	white oak	(h)

(e) at 2 pounds active ingredient per 100 gallons.
(f) at 3 pounds active ingredient per 100 gallons.
(g) at 4 pounds active ingredient per 100 gallons.
(h) at 6 pounds active ingredient per 100 gallons.

AQUATIC WEEDS CONTROLLED:

PFDABAA	cattail	(j)
PCACJAA	phragmites	(k)
PAAAACE	tules	
PECABBA	waterhyacinth	(i)

(i) at 1 to 1.5 pounds active ingredient per acre.
(j) at 6 to 10 pounds active ingredient per acre.
(k) at 8 to 20 pounds active ingredient per acre.

NONFLOWERING PLANTS CONTROLLED:

PSTABBC	scouringrush	(c)

(c) at 6 pounds active ingredient per acre.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	AGRICULTURAL PREMISES	
660000A	Uncultivated Agricultural Areas	General Information: Uncultivated agricultural areas include farm buildings, fencerows, storage areas, etc.
	1.80-5.40 (50-90% SC/S)	Broadcast or spot treatment. Apply in enough water for adequate coverage; double the spray volume in the intermountain states. The specific dosage is determined by the weeds to be controlled. May be tank mixed with atrazine; or diuron; or simazine.
	2.00-8.00 (2 lb/gal SC/L)	
	2.00-6.00 lb/ 100 gal (2 lb/gal SC/L) (50-90% SC/S)	Woody plant control. Broadcast or spot treatment. Thoroughly spray all foliage and stems to the ground line from the time the foliage is fully developed until plants begin to go dormant.
	ORNAMENTALS	
35141AA	American Beech	
35019AA	American Elm	
35021AA	Arborvitae	
35021DA	Arborvitae (nursery stock)	
35026AA	Balsam Fir	
35026DA	Balsam Fir (nursery stock)	
35040AA	Chinese Elm	
3-305AA	Convex Leaf Holly	
3-043AA	Dogwood	
35044AA	Douglas-Fir	
35044DA	Douglas-Fir (nursery stock)	
35045AA	Eastern Hemlock	
3-055AA	Firethorn	
3-058DA	Firethorn (nursery stock)	
35061AA	Fraser Fir	
35061DA	Fraser Fir (nursery stock)	
34080AA	Japanese Holly	
35187AA	Japanese Maple	
35073AA	Juniper	
35073DA	Juniper (nursery stock)	
35192AA	London Plane Tree	

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	American Beech cluster (continued)	
35090AA	Norway Spruce	
35090DA	Norway Spruce (nursery stock)	
34102AA	Oleander	
34102DA	Oleander (nursery stock)	
35106AA	Red Pine	
35106DA	Red Pine (nursery stock)	
35107AA	Red Spruce	
35107DA	Red Spruce (nursery stock)	
35113AA	Scotch Pine	
35113DA	Scotch Pine (nursery stock)	
35211AA	Silver Maple	
35119AA	Sycamore	
34137AA	Viburnum	
34137DA	Viburnum (nursery stock)	
35227AA	White Ash	
35127AA	White Spruce	
35127DA	White Spruce (nursery stock)	
35130AA	Yew	
35130DA	Yew (nursery stock)	
	0.90-1.05 (90% SC/S) (2 lb/gal SC/L) (15% WP)	Directed spray. Apply to small weeds in spring or early summer in 80 to 100 gallons of water, to wet the foliage thoroughly. Cut or mow tall weeds to the ground line, remove cuttings and spray regrowth 1 or 2 weeks later. Reapply when any regrowth is 6 to 12 inches tall. May be tank mixed with simazine. May be formulated with simazine.
35000DA	Ornamental Hardwoods (nursery stock)	
	8.00-8.13 (2 lb/gal SC/L) (50-90% SC/S)	Directed spray for chrysanthemum control. Apply in 100 gallons water when weeds are 4 to 6 inches tall. Keep spray off hardwood stock.

AMITROLE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
33010AA	Ornamental Lawns	
	-- (0.36-1% PrL)	Spot treatment to individual weed clumps. Spray target weeds only. Dig up treated quackgrass to a depth of 1 to 6 inches 2 weeks after application.
	0.63 lb a.i./ 5,000 sq.ft (2 lb/gal SC/L)	Lawn renovation. Apply in late summer to early fall when plants are actively growing in 25 to 30 gallons of water. Water heavily if no rain falls within 5 to 7 days. Dig, rotovate or plow 10 to 14 days after application and reseed. Keep spray off desirable vegetation.
32000AA	Ornamental Plants	
	0.90 (90% SC/S)	Directed spray. Apply to weeds in plantings in median strips. Tank mix with simazine. Where johnsongrass or bermudagrass is a problem, may be tank mixed with diuron; or monuron.
32000DA	Ornamental Plants (nursery stock)	
	0.90 (90% SC/S)	Directed spray. Tank mix with simazine.
	RIGHTS-OF-WAY	
67019OA	Rights-of-Way	
	1.80-5.40 (50-90% SC/S)	Broadcast or spot treatment. Apply in enough water for adequate coverage; double the spray volume in the intermountain states. The specific dosage is determend by the weeds to be controlled. May be tank mixed with atrazine; bromacil; diuron; monuron; simazine; atrazine and sodium 2,3,6-trichlorophenylacetate; bromacil and 2,4-dichlorophenoxyacetic acid esters or amines; bromacil and diuron; bromacil and sodium 2,3,6-trichlorophenylacetate; or bromacil and diuron and 2,4-dichlorophenoxyacetic acid esters or amines.
	2.00-8.00 (2 lb/gal SC/L)	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Rights-of-Way (continued)	
1.00-2.00 (25% WP)	Broadcast or spot treatment. Apply in 20 to 100 gallons of water. Use the higher dosage for prolonged control or when weeds are 6 to 8 inches tall. Formulated with linuron.
1.49-2.97 (0.33 lb/gal FlC)	Broadcast or spot treatment. Apply in 100 gallons of water. Use the lower dosage where annual rainfall is less than 15 inches and the higher dosage where annual rainfall is between 15 to 20 inches. Formulated with ammonium 2,3,6-trichlorophenylacetate and atrazine.
2.00-6.00 lb/ 100 gal (2 lb/gal SC/L) (50-90% SC/S)	Woody plant control. Broadcast or spot treatment. Thoroughly spray all foliage and stems to the ground line from the time the foliage is fully developed until plants begin to go dormant.
670110A **Paved Areas**	
1.98-2.97 (0.33 lb/gal FlC)	Prepaving treatment. Destroy existing weed growth, grade and level area to be surfaced. Apply in at least 300 gallons of water per acre. Apply asphalt or cement cover as soon as possible. Formulated with ammonium 2,3,6-trichlorophenylacetate and atrazine.
COMMERCIAL AND INDUSTRIAL PREMISES	
670000A **Noncrop Areas**	
	General Information: Noncrop areas include parking lots, tank farms, lumber yards, storage areas, fencerows, etc.
1.80-5.40 (50-90% SC/S)	Broadcast or spot treatment. Apply in enough water for adequate coverage; double the spray volume in the intermountain states. The specfic dosage is determined by the weeds to be controlled. May be tank mixed with atrazine; bromacil; diuron; karbutilate; monuron; simazine; atrazine and sodium 2,3,6-trichlorophenylacetate; bromacil and 2,4-dichlorophenoxyacetic acid esters or amines; or bromacil and sodium 2,3,6-trichlorophenylacetate.
2.00-4.00 (2 lb/gal SC/L)	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Noncrop Areas (continued)	
1.49-2.97 (0.33 lb/gal FlC)	Broadcast or spot treatment. Apply in 100 gallons of water. Use the lower dosage where annual rainfall is less than 15 inches and the higher dosage where annual rainfall is between 15 to 20 inches. Formulated with ammonium 2,3,6-trichlorophenylacetate and atrazine.
3.96 (0.44 lb/gal FlC)	Broadcast or spot treatment. Apply in at least 50 gallons of water. Formulated with simazine.
0.90-3.00 (0.3 lb/gal SC/L)	Broadcast or spot treatment. Apply in 20 to 100 gallons of water. Formulated with dimethylamine bromacil and dimethylamine 2,3,6-trichlorophenylacetate.
2.00-6.00 lb/ 100 gal (2 lb/gal SC/L) (50-90% SC/S)	Woody plant control. Broadcast or spot treatment. Thoroughly spray all foliage and stems to the ground line from the time the foliage is fully developed until plants begin to go dormant.
670110A **Paved Areas**	
1.98-2.97 (0.33 lb/gal FlC)	Prepaving treatment. Destroy existing weed growth, grade and level area to be surfaced. Apply in at least 300 gallons of water per acre. Apply asphalt or cement cover as soon as possible. Formulated with ammonium 2,3,6-trichlorophenylacetate and atrazine.
DOMESTIC DWELLINGS, MEDICAL FACILITIES AND SCHOOLS	
670000A **Noncrop Areas**	
	General Information: Noncrop areas include areas along walks, fencerows, buildings, patios, and driveways, etc.
-- (0.36-1% PrL)	Spot treatment to individual weeds. Spray target weeds only. Dig up treated quackgrass to a depth of 5 to 6 inches 2 weeks after application.
1 pt product/ 1-2 gal	Spot treatment. Apply using a sprayer or watering can.

AMITROLE

Site, Dosage and Formulation (lb a.i./A) (1% EC)	Tolerance, Use, Limitations

FOREST, CHAPARRAL, NONAGRICULTURAL AND WASTELANDS

30126AA American Beech
30127AA American Elm
30119AA Arborvitae
30128AA Balsam Fir
30039AA Douglas-Fir
30077AA Eastern Hemlock
30129AA Fraser Fir
30050AA Juniper
30130AA Norway Spruce
30103AA Red Pine
30125AA Red Spruce
30113AA Scotch Pine
30131AA Silver Maple
30066AA Sycamore
30132AA White Ash
30108AA White Spruce
30073AA Yew

0.90-1.05 (90% SC/S) (2 lb/gal SC/L) (15% WP)	Directed spray in forest plantations. Apply to small weeds in spring or early summer in 80 to 100 gallons of water, to wet the foliage thoroughly. Cut or mow tall weeds to the ground line, remove cuttings and spray regrowth 1 or 2 weeks later. Reapply when any regrowth is 6 to 12 inches tall. May be tank mixed with simazine. May be formulated with simazine.

AQUATIC AREAS

General Warnings and Limitations: Do not allow spray or drift to contaminate water which will be used for irrigation, drinking or other domestic purposes. Do not apply to water where fish are present.

(Moving Water)

30013MB Drainage Canals
30033MB Drainage Ditches
Marshes

6.00 (2 lb/gal SC/L)	Cattail control in North Central and Eastern States. Broadcast after catkins are fully developed until frost. Do not disturb treated plants. Spot treat any regrowth. Apply in 300 gallons of water by ground and in 10 gallons of water by aerial equipment.

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Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Drainage Canals cluster (continued)	
8.00-10.00 (2 lb/gal SC/L)	Cattail control in Southwestern and Western States. Broadcast after catkins are fully developed until frost. Do not disturb treated plants. Spot treat any regrowth. Apply the lower dosage in 400 gallons of water by ground and the higher dosage in 15 gallons of water by aerial equipment.
7.20-9.90 (90% SC/S)	Cattail control. Broadcast after catkins are fully developed until frost. Do not disturb treated plants. Spot treat any regrowth. Apply in 300 to 400 gallons of water by ground and in 15 gallons of water by aerial equipment.
1.80-4.50 (90% SC/S)	Cattail, phragmites and tules control. Broadcast. Use the higher dosage in flooded sites and the lower dosage in nonflooded sites. Tank mix with sodium dalapon.
8.00 (2 lb/gal SC/L)	Phragmites control in North Central and Eastern States. Broadcast after plants are 30 inches tall until early fruiting stage. Apply in 100 gallons of water by ground and in 5 to 10 gallons of water by aerial equipment.
15.00-20.00 (2 lb/gal SC/L)	Phragmites control in the Atlantic coast region. Broadcast after plants are 30 inches tall until early fruiting stage. Apply the lower dosage in 300 gallons of water by ground and in 5 gallons of water by aerial equipment to nonflooded sites. Apply the higher dosage in 300 gallons of water by aerial equipment to flooded sites.
1.00-1.50 (2 lb/gal SC/L)	Waterhyacinth control in the Southeastern States. Broadcast in April to wet the weeds and the shoots under the plants thoroughly. Apply in 200 gallons of water by ground and in 5 gallons of water by aerial equipment.
Drainage Ditches	See Drainage Canals cluster.
(Marshes, Estuaries, Shorelines)	
Marshes	See (Moving Water), Drainage Canals cluster.
(Adjacent to Water)	
Ditch Banks	See (Moving Water), Drainage Canals cluster.

AMITROLE

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
AERIAL AND TANK MIX APPLICATIONS	
001500 Aerial Applications	
--	Refer to AQUATIC AREAS All sites
900300 Tank Mix	
--	Refer to AGRICULTURAL PREMISES All sites ORNAMENTALS American Beech cluster, Ornamental Plants, Ornamental Plants (nursery stock) RIGHTS-OF-WAY Rights-of-Way COMMERCIAL AND INDUSTRIAL PREMISES Noncrop Agricultural Areas FOREST, CHAPARRAL, NONAGRICULTURAL AND WASTELAND All sites AQUATIC AREAS All sites

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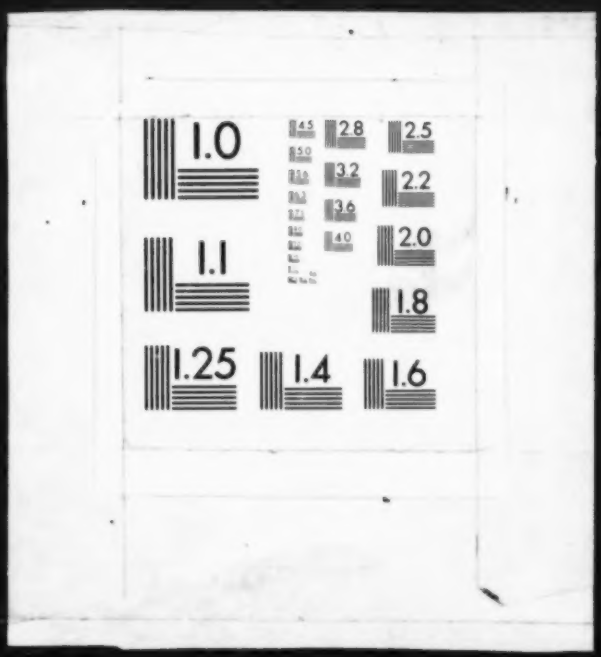

AMITROLE

Listing of Registered Pesticide Products by Formulation

90% technical chemical
amitrole (004401)
000241-00222 000264-00238 002749-00071 009319-00017

95% technical chemical
amitrole (004401)
007173-00093

15% wettable powder
amitrole (004401) plus simazine (080807)
000264-00124

25% wettable powder
amitrole (004401) plus linuron (035506)
000264-00246

0.33 lb/gal flowable concentrate
amitrole (004401), atrazine (080803) plus ammonium 2,3,6-trichlorophenylacetate (082606)
000264-00172

0.44 lb/gal flowable concentrate
amitrole (004401) plus simazine (080807)
000264-00196

1% flowable concentrate
amitrole (004401) plus simazine (080807)
000264-00156

0.3 lb/gal soluble concentrate/liquid
amitrole (004401), dimethylamine bromacil (012304) plus dimethylamine 2,3,6-trichlorophenylacetate (082605)
000264-00244

2 lb/gal soluble concentrate/liquid
amitrole (004401)
000264-00060 000264-00135 000264-00226 002749-00137
010337-00005

50% soluble concentrate/solid
amitrole (004401)
000264-00068 002749-00216

90% soluble concentrate/solid
amitrole (004401)
000241-00057 000241-00168 000264-00119 002749-00073
007173-00142 009319-00011

0.36% pressurized liquid
amitrole (004401)
007701-00033

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